

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

KING PHARMACEUTICALS, INC.;
KING PHARMACEUTICALS RESEARCH
AND DEVELOPMENT, INC.; ELAN
CORPORATION, PLC; and ELAN
PHARMA INTERNATIONAL LTD,

Plaintiffs,

V.

SANDOZ INC.,

Defendant.

Civil Action No. 09-3587 (GEB)

MEMORANDUM OPINION

BROWN, Chief Judge

This matter comes before the Court on requests for claim construction from Plaintiffs King Pharmaceuticals, Inc., King Pharmaceuticals Research and Development, Inc., Elan Corporation, PLC, and Elan Pharma International, LTD (collectively “Plaintiffs”); and Sandoz Inc. (“Defendant”). The parties submitted an amended Joint Claim Construction Chart, which identified five disputed terms. (Doc. Nos. 25, 31.) On April 29, 2010, the parties filed their opening claim construction briefs (Doc. Nos. 27, 29) and on June 30, 2010, the parties filed their reply briefs. (Doc. Nos. 41, 42.)

I. BACKGROUND

This is a patent infringement case concerning a drug product known as Avinza. Avinza is a sustained release formulation of morphine that delivers relatively constant levels of the drug

to the patient. This Hatch-Waxman litigation arises from Sandoz filing an Abbreviated New Drug Application (“ANDA”) with the FDA pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, sale, and importation of a generic form of Avinza. Sandoz filed a paragraph IV certification, asserting that the claims of U.S. Patent No. 6,066,339 (“the ’339 patent”) are invalid, unenforceable, or will not be infringed by the proposed activities described in Sandoz’s ANDA.

This Court held a Markman hearing on September 27, 2010, and construed all but two terms. This opinion addresses the remaining two terms. Those terms are “core” and “core being coated with a rate-controlling polymer coat.” Both terms appear in claim 1, which states:

1. An oral morphine multiparticulate formulation for once-daily administration to a patient, comprising sustained release particles each having a core containing water soluble morphine and an osmotic agent, the core being coated with a rate-controlling polymer coat comprised of ammonia methacrylate copolymers in an amount sufficient to achieve therapeutically effective plasma levels of morphine over at least 24 hours in the patient wherein the said osmotic agent is an organic acid.

(‘339 patent, 20:59-67 (emphasis on disputed terms).)

This Court has previously construed terms in this patent in *King Pharmaceuticals, Inc. v. Actavis, Inc.*, Civil Action No. 07-5041 (GEB) (the Actavis action), including the term “core.”

II. DISCUSSION

A. Standard of Review

The first step in a patent infringement analysis is to define the meaning and scope of the claims of the patent. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff’d*, 517 U.S. 370 (1996). Claim construction, which serves this purpose, is a matter of law exclusively for the court. *Id.* at 979. When construing claims, the court must first

consider the intrinsic evidence. Specifically, the focus of the court's analysis must begin and remain on the language of the claims, "for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2).

Generally, there is a presumption that the words of a claim will receive the full breadth of their ordinary meaning. *NTP, Inc. v. Research In Motion, Ltd.*, 392 F.3d 1336, 1346 (Fed. Cir. 2004). The ordinary meaning may be derived from a variety of sources, including: the claim language, the written description, drawings, the prosecution history, and dictionaries or treatises. *Id.* This presumption may be rebutted if the patentee acted as his or her own lexicographer by clearly setting forth a definition of the claim term that differs from its ordinary and customary meaning. *Brookhill-Wilk I, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298-99 (Fed. Cir. 2003). To rebut the presumption, the patentee's intent must be clearly expressed in the specification. *Merck & Co, Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005). When a patent applicant specifically defines a claim term in its description of its invention, that definition controls. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (*en banc*) ("In such cases, the inventor's lexicography governs."). The Federal Circuit has "repeatedly encouraged claim drafters who choose to act as their own lexicographers to clearly define terms used in the claims in the specification." *Sinorgchem Co. v. ITC*, 511 F.3d 1132, 1136 (Fed. Cir. 2007).

When the patentee has not provided an explicit definition of a claim term, the words of a claim are given their plain and ordinary meaning to a person of ordinary skill in the art. *Vitronics*

Corp. v. Conceptoronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The person of ordinary skill in the art is deemed to read the claim terms in the context of the entire patent, including the specification. *Phillips*, 415 F.3d at 1313. However, a court should not limit the claims to the embodiments disclosed in the specification. *See Phillips*, 415 F.3d at 1323.

A court may also consider extrinsic evidence when an analysis of the intrinsic evidence alone does not resolve the ambiguities of a disputed claim term. *Id.* at 1582-83. While a court may rely on extrinsic evidence to construe a claim, “what matters is for the court to attach the appropriate weight to be assigned to those sources.” *Phillips*, 415 F.3d at 1324. Extrinsic evidence may never be used to contradict intrinsic evidence. *Id.* at 1322-23.

B. Analysis

The majority of the terms will be construed as set forth on the record during the Markman hearing, as reflected in the accompanying order. However, two terms require additional discussion; they are: (1) “core” and (2) “core being coated with a rate-controlling polymer coat.” The Court construes “core” to mean “*an inner portion*” and finds that “core being coated with a rate-controlling polymer coat” does not require construction at this time for the reasons set forth below.

1. Core

Plaintiffs propose that “core” should be construed to mean “*an inner portion*,” while the Defendant’s construction is “*an inner portion of the particle not including the polymer coating*.” (Joint CC Chart at 7; Doc. No. 31.) The dispute is over whether Defendant’s additional limitation, which excludes a polymer coating from the core, should be part of the definition of

the term “core.” The Court construes this term to mean “*an inner portion*,” because it is in line with the ordinary meaning of the term, and, while Defendant is correct that the specification does not expressly or impliedly disclose a polymer coating within the core, Defendant’s construction imports a limitation from the specification into the claim.

The Court construes “core” as “*an inner portion*” because that construction gives full breadth to the ordinary meaning of the term. *See NTP, Inc.*, 392 F.3d at 1346 (there is a presumption that terms are given the full breadth of their ordinary meaning). “Core” certainly does not disclose the contents of the core, only its location – it is inside something. This ordinary meaning is supported by the term’s context in the claim. The claim states that the core is “coated with a rate-controlling polymer coat,” placing the core inside a polymer coat. (‘339 patent, 20:62-64; *see also* ‘339 patent, 5:63-67.)

The Defendant is correct that the specification discloses no polymer coat in the core. The most complete description of the core (the “specific description”), cited by both parties, does not point to the possibility of an internal coating. That portion states:

The core, herein referred to as applied beads or IR beads, can be formed by building up the morphine active agent, osmotic agent, and, if desired, any pharmaceutically acceptable excipient(s) such as binders, surfactants and lubricants on an inert core. The inert core is preferably a non-pareil seed of sugar/starch having an average diameter in the range 0.2-1.4mm, more especially, 0.3-0.8mm, most especially 0.5-0.6mm.

The morphine active agent, the osmotic agent and, if desired, pharmaceutically acceptable excipient(s) are blended to form a homogenous powder herein referred to as the active blend. This blend can then be applied to the inert core using an application solution.

(‘339 Patent, 5:19-31 (emphasis added); *see also* ‘339 patent, 7:64-67, 10:37-50, 14:39-53, 8:65-67, 9:57-59 (the patent’s examples do not have polymer coatings within the core).) The

excipients mentioned in the description are substances used to aid medical delivery of an active agent and could include polymers such as those that make up the coating. (*See, e.g.*, '339 Patent, 7:49-59 (listing the polymer coating as an excipient in an example).) Thus, the first paragraph implies that the polymer could be one of the layers that are built up on the core. However, when read in context with the second paragraph, this description requires the excipients to be blended with the active agent to form a homogenous powder before they are built up. Consequently, this portion of the specification does not disclose a coating because the layers could only be built with a homogenous mixture that includes the active ingredient and the polymers.

Despite this language, Defendant's construction improperly imports a limitation of the specification into the claim. *See Phillips*, 415 F.3d at 1323. This conclusion is supported both by the specification, which in other passages describes "core" more broadly, and the claim language itself, which provides limits on the core that suggest that when the drafter intended to limit the core, he did so using the claim language itself and not the written description.

Several portions of the specification disclose a core without the limitations contained in the specific description. The specification describes the core as "a core of water soluble morphine and optionally an osmotic agent" ('339 patent, 3:38-42) and as "a core containing water soluble morphine and an osmotic agent[.]" (*Id.* at 2:60-61.) These passages, while short, do not imply that a polymer coating could not be present; they are inclusive, not exclusive. The claim mirrors this inclusive language. (*Id.* at 20:60-67.) Thus, the Defendant's proposed limitation, which may be implied in the specific description, is far from omnipresent in the specification as a whole.

Further, to the extent the drafter intended to put limitations on the type of “core” he claimed, he put those limitations in the claims themselves. (‘339 patent, 20:60-67.) This is demonstrated by the fact that *some* but not all of the limitations that are present in the specific description are present in the claims. Claim 1 provides that each sustained release particle has:

a core containing water soluble morphine and an osmotic agent, the core being coated with a rate-controlling polymer coat comprised of ammonia methacrylate copolymers in an amount sufficient to achieve therapeutically effective plasma levels of morphine over at least 24 hours in the patient wherein the said osmotic agent is an organic agent.

(‘339 patent, 20:60-67.) Thus, the claim itself puts limits on the core – it contains water soluble morphine and an osmotic agent, and that agent is an organic acid. This strongly suggests that, to the extent that the drafter intended limits to be placed on the term “core,” he put them in the claim following the term itself. Because the claim language surrounding the term “core” sets forth the type of core the patentee intended to claim, there is no reason the Court should import other limitations into the term itself. Consequently, this Court rejects Defendant’s construction because it imports a limitation from part of the specification into the claims. *See Phillips*, 415 F.3d at 1323.

Thus, the Court construes “core” to mean “*an inner portion*” because it is in line with the full breadth of the term’s ordinary meaning and the specification provides no reason to narrow that construction.

The Court also notes that, despite Defendant’s concern, its construction of “core” as “*an inner portion*” is not the same as construing it “*an inner portion, including an internal polymer coat*.” Rather, the Court’s construction gives a basic meaning to the term and allows the surrounding limitations in the claim to further limit the type of core that is claimed. The

determination of whether the claims read on a product with a polymer coating in its core is a question of infringement and is not before the Court.

2. *The core being coated with a rate-controlling polymer coat*

Defendant proposes that “the core being coated with a rate-controlling polymer coat” should be construed to mean “*a coating of polymer applied on the core that controls delivery of the active ingredient.*” (*Id.*) Defendant argues that its construction should be adopted because Plaintiffs did not provide a construction. (Def’s Br. at 17; Doc. No. 29.) Plaintiffs argue that this term does not require construction because it does not have a meaning other than that of the individual words, which each have a well-understood meaning. (Joint CC Chart at 7; Doc. No. 31.)

This term does not require construction. Claim construction is not “an obligatory exercise in redundancy” and is not required where the claim terms have a well-understood meaning. *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008). Each of the words in this term has a well-understood meaning. The fact that Defendant’s construction is so similar to the claim term and changes it only to use different tenses of its root words demonstrates that those words have a well-understood meaning. Thus, construing this term would be an exercise in redundancy. *See O2 Micro Int’l*, 521 F.3d at 1362. Therefore, the Court concludes that this term does not need to be construed.

III. CONCLUSION

For the reasons stated herein, the Court will construe “core” to mean “*an inner portion*” and finds that “the core being coated with a rate-controlling polymer coat” does not require construction. The remaining terms are construed in line with the Order submitted with this opinion.

Dated: October 1, 2010

/s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.